

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE: WORLD TRADE CENTER
DISASTER SITE LITIGATION

THIS DOCUMENT APPLIES TO ALL
IN RE WORLD TRADE CENTER
DISASTER SITE LITIGATION

**AFFIDAVIT OF DAVID J.
PREZANT IN SUPPORT
OF MOTION TO MODIFY
SUBPOENA AND FOR
PROTECTIVE ORDER**

21 MC 100 (AKH)

STATE OF NEW YORK)
) SS.:
COUNTY OF KINGS)

David J. Prezant, being duly sworn, deposes and says:

Background

1. I am a physician licensed to practice in the State of New York. I am employed by the Fire Department of the City of New York ("FDNY") as Chief Medical Officer and Special Advisor to the Fire Commissioner on Health Policy. I also serve as Co-Director of the FDNY World Trade Center Medical Monitoring and Treatment Program ("MMTP") and the Principal Investigator for the FDNY World Trade Center Data Center. In addition, I am a Professor of Medicine at Albert Einstein College of Medicine and an Attending Pulmonary Physician at Montefiore Medical Center, the primary teaching hospital for Albert Einstein College of Medicine.¹

¹ A copy my *curriculum vitae* is attached as Exhibit A.

2. I submit this affidavit in support of the motion by the City of New York (“City”) to modify the subpoena issued to FDNY by the attorneys for defendant subcontractors for certain data related to studies I performed of FDNY personnel who responded to the attacks on the World Trade Center on and after September 11, 2001.

3. Maintaining the sanctity of the doctor-patient relationship is one of the most important responsibilities of any doctor. In addition, the individuals whose medical data is called for by the subpoena were given written assurances of confidentiality as part of a consent process mandated by federal statutes governing federally funded research on human subjects. Thus, ensuring the confidentiality of the medical information of FDNY personnel who are participants in the studies is of vital importance.

4. By way of background, I was at the World Trade Center on September 11, 2001 taking care of FDNY firefighters and EMS rescue workers. I was present during the collapse of the towers. Since that day, I have in large part devoted my entire clinical and research efforts to medical monitoring and treatment of FDNY firefighters and EMS rescue workers. In October 2001, only four weeks after the attack, FDNY’s Bureau of Health Services (“BHS”) began performing standardized medical screenings on WTC rescue workers with funding provided by the City. This was the first comprehensive post-WTC exposure medical evaluation performed by any medical institution.

5. In November 2001, the Centers for Disease Control (“CDC”) awarded FDNY a grant of \$4.8 million to help fund the MMTP program for the period from 2002 to 2004. This allowed the program to include affected retirees. By February 2002, FDNY-BHS had conducted screening medical examinations on nearly 10,000 FDNY rescue workers (Fire and EMS, active and retired).

6. In July 2004, CDC's National Institute of Occupational Safety and Health ("CDC/NIOSH") awarded FDNY a grant of \$25 million to continue its MMTP program for an additional five years (2004-2009) at \$5 million per year. In 2006, CDC/NIOSH added funding for treatment and prescription medications for certain World Trade Center-related medical conditions.

7. In 2009, CDC/NIOSH provided additional funding to extend this program to June 30, 2011, and by the last year of this funding stream, the annual budget for monitoring, treatment, and data collection combined had increased to approximately \$34 million, including \$10 million for prescription medications.

8. With the passage of the Zadroga Act in 2011, the level of CDC/NIOSH funding of the MMTP remained unchanged (adjusted for healthcare inflation), but the structure of the funding changed. Effective July 1, 2011, external health care providers and prescription medications were paid for directly by the federal government, with the FDNY receiving the balance of the funding—approximately \$20 million annually—for its program and services.

9. The Fire Department's federal reporting obligations in connection with the CDC/NIOSH funding of the MMTP include providing on a monthly basis information in the aggregate, including the number of patients treated, the number of hospitalizations, if any, the number of prescriptions per medication, and the types of medical treatment. Until July 1, 2011, there was no specific reference, even a de-identified reference, in the reports to individually identifiable program participants. Under the Zadroga Act, reports continue to provide aggregate information only, but invoices to the federal government for specific WTC-covered medical services now contain an identifier number without other information, so that payments can be tracked by participant.

10. I have published over forty research papers on the health impact of the World Trade Center collapse on FDNY firefighters and EMS personnel. The papers have appeared in peer-reviewed medical journals such as the New England Journal of Medicine, the Lancet, the CDC's Morbidity and Mortality Weekly Report, Environmental Health Perspectives, CHEST, and the American Journal of Respiratory and Critical Care Medicine.

11. The research papers were the result of studies that were funded by federal grants awarded by CDC/NIOSH, a federal agency, in accordance with the Public Health Service Act, 42 U.S.C. sec. 241. The FDNY entered into a contract with Montefiore Hospital under which Montefiore employees with expertise in medical statistics and research analyzed the data collected as part of the MMTP.

The Medical Data Sought by the Subpoena

12. The subpoena calls for the disclosure of medical and demographic information collected from nearly 15,000 FDNY firefighters and EMS personnel participating in the MMTP program to monitor the medical condition of, and provide medical treatment and prescription drugs to, active and retired Fire and EMS personnel who participated in the rescue and recovery efforts on and after September 11, 2001. The program provides for proactive monitoring of FDNY participants' medical condition for specific conditions that may be related to World Trade Center exposure (*e.g.*, aerodigestive conditions, musculoskeletal disorders, and mental health conditions). Participants are eligible for monitoring, treatment, prescription drug benefits, and mental health services by virtue of their participation in World Trade Center rescue and recovery work. All health care services and prescription drugs are provided at no charge to the participants.

13. The FDNY also performs medical monitoring to assess the fitness for duty of its personnel and when indicated provides or authorizes treatment for other line-of-duty service-related injuries or illnesses. There is some overlap between these functions (monitoring, treatment, and the MMTP program), but any information that is shared is treated as confidential.

Assurances of Medical Confidentiality Given to FDNY Participants

14. Much of the medical and demographic data sought by the subpoena was provided by the participants based on assurances that the information would be kept confidential and not be disclosed to anybody unrelated to the research. At a meeting in October 2001, as I asked FDNY first responders for their participation in the WTC monitoring I wanted to conduct, I personally assured a group of 500 firefighters and EMS workers, chosen to represent all of the nearly 15,000 of those individuals, that the medical information I obtained from studying them would be kept strictly confidential.

15. Assurances of privacy were also made to the participants in writing on the informed-consent form signed during their initial evaluations for the program. These consent forms were approved by an external and independent Institutional Review Board for the Protection of Human Subjects ("IRB"). IRBs are federally mandated entities for institutions receiving public funding for research involving human subjects.² The function of the IRB is to review and approve or reject proposed research protocols. This includes approval of the consent forms that were signed by the study participants. As the research subjects were informed in the consent form for one of the studies, the IRB's review "protects your rights as a research participant and further protects the

² See 42 U.S.C. § 289 and implementing regulations at 45 CFR § 46.101 et seq.

medical confidentiality of your results.”³ The consent forms further provided the participants with assurances that “you can not be identified . . . by the FDNY . . . , the CDC or any individual”⁴ and “no published or unpublished report . . . will include any material that will permit your identification.”⁵

16. Beyond the assurances of confidentiality provided to the FDNY participants by the researchers and the independent IRB, one of the studies that is the subject of the subpoena—the study of stress-related health disorders—has a federal Confidentiality Certificate issued by the Department of Health and Human Services to the New York City Fire Department. Under federal law, the holder of this certificate “may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals.”⁶ The Certificate provides that the researchers are “hereby authorized to protect the privacy of individuals who are the subject of that research by withholding their names and other identifying

³ See, e.g., Individual’s Informed Consent to Participate as a Subject in Clinical Research for the study entitled *Medical Surveillance In New York City Fire Department Employees Exposed To Dust During The World Trade Center Collapse*, attached here as Exhibit B.

⁴ Montefiore Medical Center, Individual’s Informed Consent to Participate as a Subject in Clinical Research for the study entitled *Airway Hyperreactivity In NYC Fire Department Employees Exposed To The World Trade Center Collapse*, attached here as Exhibit C.

⁵ Montefiore Medical Center, Individual’s Informed Consent to Participate as a Subject in Clinical Research for the study entitled *Stress Related Health Problems In NYC Firefighters, EMS Workers And Officers Exposed To The World Trade Center Attack*, attached here as Exhibit D.

⁶ Confidentiality Certificate Issued to Employees of New York City Fire Department, et al., conducting research known as *Stress Related Health Problems In NYC Firefighters, EMS Workers And Officers Exposed To The World Trade Center Attack* (quoting Section 301(d) of the Public Health Services Act (42 USC § 241(d))), attached here as Exhibit E.

characteristics from all persons not connected with the conduct of that research”⁷

Based on this Certificate, the study participants were assured in the IRB-approved informed-consent form that “a Certificate of Confidentiality from the Federal Government . . . protects against the involuntary release of information about you collected during the course of this study”; “anything you tell us will not have to be given out to anyone, even if a court orders us to do so”; and “the protection . . . is permanent (including after death)”⁸ Accordingly, I do not believe that any identifying data from the stress study should be obtainable by the subpoenaing parties.

Use of HIPAA Standards for De-Identifying Protected Health Information Would Protect Participants’ Confidentiality

17. FDNY has adopted a confidentiality policy for its medical records, which maintains the confidentiality of all FDNY patient health records, and restricts their disclosure in a manner consistent with the principles embodied in the HIPAA privacy standards, whether or not the health care activities are formally subject to HIPAA privacy standards.⁹ This policy honors the important considerations underlying the physician-patient privilege and adheres to our promises to protect the confidentiality of the participants in our research studies. HIPAA privacy standards have become the generally accepted practice in the medical profession.

⁷ Informed Consent Form for *Stress Related Health Problems In NYC Firefighters, EMS Workers And Officers Exposed To The World Trade Center Attack*, attached here as Exhibit D.

⁸ *Id.*

⁹ See FDNY policy and procedure on Confidentiality, Use and Disclosure of Patient Health Information (A.U.C.334; EMSC OGP 113-05, November 12, 2004), attached here as Exhibit F.

18. HIPAA has two standards that we believe should be adhered to in responding to the subpoena. First, HIPAA provides that the use and disclosure of health information should be limited to the minimum amount of information needed for the purpose for which it is to be used, or responsive to the disclosure requested.

19. Second, information should not be disclosed that identifies the patient or provides details about the patient that in combination could be used to learn the patient's identity. The HIPAA regulations state that protected health information includes demographic information collected from an individual which "identifies the individual" or "[w]ith respect to which there is a reasonable basis to believe the information can be used to identify the individual."¹⁰

20. In contrast, HIPAA does not restrict use or disclosure of health information which is "de-identified."¹¹ De-identified health information "does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual"¹² According to the regulations, "identifiers" which should be removed include "[a]ll elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89. . . ."¹³ Also to be removed are "[a]ll geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code"¹⁴ Finally, there is a catchall in the regulations with

¹⁰ 45 CFR § 160.103 (under definition of "Individually identifiable health information," subpart 2(i),(ii)).

¹¹ 164.502.

¹² 164.514(a).

¹³ 164.514(b)(2)(i)(C).

¹⁴ 164.514(b)(2)(i)(B).

respect to the removal of identifying information, requiring removal of “[a]ny other unique identifying . . . characteristic”¹⁵

21. While I understand that the subpoenaing parties have agreed to the redaction of directly identifying information (*i.e.*, name and social security number), indirectly identifying characteristics that can be used to identify FDNY participants should also be removed. Because the FDNY population is a finite universe of known individuals, the disclosure of medical information combined with indirect identifiers such as sex, race, height, place of residence, and dates of birth, death, hire, and retirement, could readily be used to identify individuals participating in the studies. Street address alone would be sufficient to identify most participants, especially when combined with other identifying information such as age, race, or height.

22. The more that FDNY is required to disclose indirectly identifying information, the more likely it will be that large numbers of participants can be identified from that information. To maintain the confidentiality of those individuals’ medical records, it is necessary to withhold the indirectly identifying data regarding the participants.


The Subpoenaing Parties Have No Apparent Need for Either Directly-Identifying or Indirectly-Identifying Data

23. In accordance with the HIPAA principle that use and disclosure of health information should be limited to the minimum amount of information needed for the purpose for which it is to be used, the participants’ directly identifying and indirectly identifying demographic information (identified above) should be withheld on the grounds that there is no apparent need for this information.

¹⁵ 164.514(b)(2)(i)(R).

24. As a general matter, there is no apparent reason why the address, race, sex, height, and dates of birth, death, hire, and retirement are needed for the subpoenaing parties to be able to review and analyze the type of pulmonary research and study done utilizing the data. Some of the demographic information—race, sex, height—was useful to the researchers only to determine the predicted pulmonary measurements of the study participants. Pulmonary function measurements are routinely expressed and analyzed as percent-predicted based on equations developed by independent researchers as part of what is known as the NHANES project and are widely used throughout the world. Predicted pulmonary measurements at FDNY are calculated using NHANES III objective formulas based on patient demographics. Since I am told the City is producing the absolute and percent-predicted values, the subpoenaing parties have no apparent need for the demographic data.

25. FDNY is willing to provide the subpoenaing parties the opportunity to conduct statistical sampling of the predicted pulmonary measurements to verify that the calculations were performed correctly.



David J. Prezant

Sworn to and subscribed
before me this 21st day of
December 2011.



Notary Public

Allison Julia Chen
Notary Public, State of New York
No. 02CH8210012
Qualified in New York County
Commission Expires 8/10/13